

Remarks

Upon entry of this amendment, claims 16-21 and 24-42 will be pending in the application.

The specification is amended to insert the titles of the Example compounds as named with the program currently used by Applicants, i.e., ACD, via Isis Draw. These names correspond to, and are supported by, the structure and description in the respective examples.

Claims 28 and 29 are withdrawn from consideration and are amended to clarify their dependent form. New claims 32 and 33 are added to recite embodiments of R^A. Support is found throughout the specification, including in the claims as originally filed and in Examples 26, 34 and 41. New claims 34-42 are added, support being found throughout the specification including original claims 1, 9, 10, and 12, and the examples.

The claims are further amended as discussed below, and otherwise to make idiomatic revisions.

No new matter is added.

Applicants reserve the right to prosecute, in one or more patent applications, any canceled claims, claims to non-elected inventions, claims as originally filed, and any other claims supported by the specification.

Election/Restriction (page 2 of the Office Action)

The Examiner acknowledges Applicants' election of Group III. Claims 28-29 are withdrawn from prosecution as being drawn to a non-elected invention. The Examiner recommends cancellation of the non-elected subject matter, noting that Applicants have to replace R⁵ with the core structure which is permitted substitution according to the specification.

Applicants have amended Claim 16 to insert the structure corresponding to the elected group III. Support is found for example in Examples 37-39 and 41-42.

Claim Rejections – 35 USC 112 1st paragraph (pages 3-8 of the Office Action)

Claims 25 and 30 are rejected under 35 USC 1st paragraph because, according to the Examiner, the specification does not reasonably provide enablement for a method of treating bacterial infections generally. The Examiner admits that the specification is enabling for a method of treating a bacterial infection due to organisms selected from *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*,

Enterococcus faecalis, *Enterococcus faecium*, *Haemophilus influenzae*, *E. coli*, and *Moraxella catarrhalis* Ravasio (based on the antimicrobial activity provided in page 97).

Preliminarily, Applicants note that the biological data appearing on pages 97-98 does not include *Enterococcus faecium*.

Solely to advance prosecution, Applicants have amended claims 25 and 30 to recite treating bacterial infection due to organisms selected from *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterococcus faecalis*, *Haemophilus influenzae*, *E. coli*, or *Moraxella catarrhalis*. Support for this amendment is found at pages 97-98. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim rejections - 35 USC 112 2nd paragraph (pages 8-9 of the Office Action)

Claims 16-21, 23 and 25-31 are rejected under 35 USC 112, 2nd paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Examiner objects to the term “acyl” and “substituted bicyclic carbocyclic or heterocyclic ring system” in claim 16. The Examiner recommends recitation of specific rings as done in claim 17.

Solely to advance prosecution, Applicants have amended claim 16 to recite the definition of “acyl”. Support is found in the specification at page 14, lines 4-5.

Applicants respectfully submit that the term “substituted bicyclic carbocyclic or heterocyclic ring system” is defined in the claim by specifying the embodiments of Z¹-Z⁵. Applicants respectfully submit that one skilled in the art would understand the scope of this term and claim 16, such that no issue under 35 USC 112, 2nd paragraph exists. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim objections (page 9-of the Office Action)

The Examiner objects to claim 24 for certain informalities, such as alleged typographical errors, set forth in the Office Action.

The specification is being amended to insert the titles of the Example compounds as named with the program currently used by Applicants, i.e. ACD, via Isis Draw. These names correspond to the structure and description in the respective examples. Claim 24 is amended to recite the names of the compounds according the ACD program, including the free form, pharmaceutically acceptable salts thereof, and pharmaceutically acceptable N-oxides thereof. New claim 40 recites the corresponding hydrochloride salts.

Reconsideration and withdrawal of the objection is respectfully requested.

Double patenting (page 10-11 of the Office Action)

The Examiner rejects claims 16-21, 23, 25-27 and 30-31 on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-8 and 10-11 of U.S. Patent No. 7,141,564. The Examiner also rejects claims 16-21, 25-27 and 30-31 on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-7 and 9-12 of U.S. Patent No. 6,962,917. In both cases, the Examiner alleges that the claims are not patentably distinct from each other because there is significant overlap between the stated claims.

Applicants respectfully traverse the rejection. First, Applicants respectfully submit that the test for double patenting is not that “there is significant overlap” between claim sets. Rather, the instant claims must be obvious over the patented claims.

a) U.S. Patent No. 7,141,564

In Applicants’ claim 16, the provisos relating to specific features of R^A exclude subject matter disclosed (and claimed) in the ‘564 patent claims. In particular, the proviso (ii) excludes the subject matter of the ‘564 claims. In the ‘564 claims, one of Z¹, Z², and Z³ is N, one of the remainder of Z¹, Z², Z³, Z⁴, and Z⁵ is CR^{1a}, and the remainder are CH. Thus, the ‘564 compounds have a quinazolin-4-yl, cinnolin-4-yl, 1,5-naphthyridin-4-yl, 1,7-naphthyridin-4-yl, or 1,8-naphthyridin-4-yl ring in the position corresponding to Applicants’ group R^A. In Applicants’ claims, according to proviso (ii) when R^A is one of such optionally substituted groups, the substituents on that group, or R³ are as defined in proviso (ii), that is:

it is substituted by at least one hydroxy (C₁₋₆)alkyl, cyano or carboxy group at the 2-, 5-, 6-, 7- or 8-position as available; or

it is substituted by at least one trifluoromethoxy group; or

R³ is halogen.

In contrast, in the ‘564 claims, cyano, hydroxymethyl, and carboxy as R¹/R^{1a} substituents are only proposed in the Z⁵ (i.e., 3-) position; R¹ and R^{1a} do not cover trifluoromethoxy; and R³ does not cover halogen. The presently claimed compounds are not taught or suggested by the ‘564 claims, such that no obviousness-type double patenting exists. Reconsideration and withdrawal of the rejection is respectfully requested.

b) U.S. Patent No. 6,962,917

The present claims recite compounds of formula (I) which have a cyclohexyl or cyclohexenyl structure, as shown in claim 16. Compounds having such a moiety are not taught or suggested by the '917 patent claims. Rather, the '917 claims have a piperidine ring in the position corresponding to Applicants' cyclohexyl/cyclohexenyl ring. Thus, no obviousness-type double patenting exists. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion:

All issues raised by the Examiner have been addressed. Should any issues remain to be resolved in the present application, the Examiner is invited to contact the undersigned Attorney for Applicants.

Respectfully submitted,

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